## Remarks

Claims 1 to 8 are pending.

The Examiner again rejected claims 1 to 8 under 35 U.S.C. § 112, first paragraph, as allegedly not enabling for prodrugs and solvates.

In response, applicants traverse the Examiner's rejections. The term "prodrug" and "solvate" are defined and fully enabled by the specification, *inter alia*, on pages 132 and 134 and well within the ability of one of skill in the art to make and use the claimed invention based on the disclosure. The formation of solvates generally is a common aspect of the solidification of organic compounds from solvents; absolute predictability that such solvates will form is not a requirement for enablement. Furthermore, in the course of explaining the rejection, the Examiner requires for enablement of the instant claims to compounds to go far beyond the making of the prodrug, that it must be metabolized in a human at a rate and extent to produce a second substance at a "physiologically meaningful concentration" and be "clinically effective". In short, the Examiner is requiring *in vivo* human clinical testing to enable the claims. Such high levels of experimental proof regarding questions of human clinical efficacy are properly the province of the FDA, not the PTO. Applicants note that the PTO has been repeatedly reversed for rejecting for lack of enablement claims directed to compounds having pharmaceutical and biological activity. *See* M.P.E.P. § 2107 (particularly §§ 2107.01 III/IV and 2107.03, discussing the relationship of the utility and enablement requirements and the role of the FDA) and § 2164 (particularly § 2164.06). Moreover, the enablement of "prodrug" and "solvate" do not require this showing and this has been recognized repeatedly by the PTO, which has allowed similar claims containing the term "prodrug" and "solvate" for related glucocorticoid mimetic applications by at least five different examiners, *see, e.g.*, U.S. Patent Nos. 6,858,627; 6,903,215; 6,960,581; 7,074,806; 7,186,864; and 7,189,758. The Examiner argues that the merits of these patents is not before the Examiner, however, these patents have both similar disclosure with regard to prodrugs and solvates and may involve related compounds and applicants are bring this fact to the Examiner's attention to obtain consistent treatment regarding examination. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw these rejections.

Applicants respectfully submit that all the pending claims are allowable and therefore solicit a Notice of Allowance for all of the pending claims. If the Examiner feels that a telephone

interview would be helpful in advancing prosecution of this application, the Examiner is invited to contact the attorney below.

Respectfully submitted,

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August 19, 2008